

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

RICHARD BARTON, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:21-cv-00319-JRS-MG
)	
STEVE GALELLA, D.D.S.,)	
ORTHOMATRIX CORP., INC.,)	
JOHN'S DENTAL LABORATORY, INC.,)	
)	
Defendants.)	

KARAN GILL, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:21-cv-00338-JRS-MG
)	
STEVE GALELLA, et al.,)	
)	
Defendants.)	

STEPHANIE O'CONNOR, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:21-cv-00374-JRS-MG
)	
STEVE GALELLA, et al.,)	
)	
Defendants.)	

AKIKO SHOSIDO, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:21-cv-00438-JRS-MG
)	
STEVE GALELLA, et al.,)	
)	
Defendants.)	

MICHAEL HAILE, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:22-cv-00083-JRS-MG
)	
STEVE GALELLA, et al.,)	
)	
Defendants.)	

Order on Motions to Dismiss

I. Introduction and Background

Here are a set of personal injury cases in which orthodontia—allegedly—went very wrong. Five cases have been consolidated for pretrial purposes, (ECF No. 35, 66); they are substantially similar, and the Court need not differentiate amongst them here. The operative complaint is Barton's Fourth Amended Complaint, (ECF No. 53), the allegations in which are taken as true.

Defendant Dr. Steve Galella, D.D.S., is the inventor and chief promotor of an orthodontic device known as the Anterior Growth Guidance Appliance (the "AGGA"). (Compl. ¶¶ 27, 34–36, 23, ECF No. 53.) The device uses metal plates and wires to

reshape the patient's mouth, jaw, and palate, ostensibly for therapeutic purposes. (*Id.* ¶ 35.)

Galella does not simply sell his device—he sells the idea of it. The business seems to work as follows: through Defendant Orthomatrix, Inc., doing business as the Facial Beauty Institute, Galella gives lectures and seminars at which he encourages other dentists to use the AGGA in their practices. (*Id.* ¶ 32.) Dentists pay to attend. Then, by and by, one of those dentists comes across a patient who seems ripe for the AGGA treatment. The dentist consults with Orthomatrix, doing business now as Orthologix, and pays to get patient-specific images, device drawings, and a "treatment plan." (*Id.* ¶ 33.) The Orthologix specs are sent to Defendant John's Dental Laboratory, Inc., which manufactures the AGGA device to order. (*Id.* ¶ 39.) The dentist pays John's Dental for the device, and John's Dental kicks back a "royalty" to Orthomatrix and Galella. (*Id.* ¶ 40.) Finally, the dentist implants the AGGA device in the patient's mouth.

Plaintiffs are a group of such patients. They allege that their dentists implanted them with the AGGA and that the device, far from solving their orthodontic problems, gave them rather grotesque new ones. (*E.g., id.* ¶ 59.)

Now before the Court are Orthomatrix's Motion to Dismiss, (ECF No. 75), and Galella's Motion to Dismiss, (ECF No. 76). Both assert, under Rule 12(b)(2), that this Court lacks personal jurisdiction over Orthomatrix and Galella, and, under Rule 12(b)(6), that the Plaintiffs' operative complaint "fails to state a claim upon which

relief can be granted." Fed. R. Civ. P. 12(b)(2), 12(b)(6). Because the two motions are substantially identical, the Court will treat them together throughout.

II. Legal Standard

A. Rule 12(b)(2)

A Rule 12(b)(2) motion tests this Court's personal jurisdiction over the defendant. Fed. R. Civ. P. 12(b)(2). At this stage, the Court will "take the plaintiff's asserted facts as true and resolve any factual disputes in its favor." *NBA Props., Inc. v. HANWJH*, No. 21-2909, 2022 WL 3367823, at *3 (7th Cir. Aug. 16, 2022) (quoting *uBID, Inc. v. GoDaddy Grp., Inc.*, 623 F.3d 421, 423–24 (7th Cir. 2010)). However, "the plaintiff bears the burden of demonstrating the existence of jurisdiction." *Id.* (quoting *Purdue Rsch. Found. v. Sanofi-Synthelabo, S.A.*, 338 F.3d 773, 782 (7th Cir. 2003)). The Court "may consider affidavits on the issue of personal jurisdiction; both parties' affidavits are accepted as true, and where they conflict, the plaintiff is entitled to resolution in its favor." *Id.* (citing *Curry v. Revolution Lab'ys, LLC*, 949 F.3d 385, 393 (7th Cir. 2020)).

B. Rule 12(b)(6)

"A Rule 12(b)(6) motion tests 'the legal sufficiency of a complaint,' as measured against the standards of Rule 8(a)." *Gunn v. Cont'l Cas. Co.*, 968 F.3d 802, 806 (7th Cir. 2020) (citing *Runnion v. Girl Scouts of Greater Chi. & Nw. Ind.*, 786 F.3d 510, 526 (7th Cir. 2015)). Rule 8(a) requires that the complaint contain a short and plain statement showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(2). "To meet this standard, a plaintiff is not required to include 'detailed factual allegations,'"

but the factual allegations must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible if it "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). When considering a motion to dismiss for failure to state a claim, courts "take all the factual allegations in the complaint as true," *Iqbal*, 556 U.S. at 678, and draw all reasonable inferences in the plaintiff's favor, *Roberts v. City of Chicago*, 817 F.3d 561, 564 (7th Cir. 2016). Courts need not, however, accept the truth of legal conclusions, and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

That said, "the bar to survive a motion to dismiss is not high." *Gociman v. Loyola Univ. of Chi.*, 41 F.4th 873 (7th Cir. 2022) (citing *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 463 (7th Cir. 2010)). "[A] plaintiff 'receives the benefit of imagination, so long as the hypotheses are consistent with the complaint.'" *Chapman v. Yellow Cab Coop.*, 875 F.3d 846, 848 (7th Cir. 2017) (quoting *Twombly*, 550 U.S. at 563).

III. Discussion

A. Personal Jurisdiction

Galella and Orthomatrix argue that they are not within the personal jurisdiction of this Court. (Galella Br. Supp. 8, ECF No. 77; Orthomatrix Memo 16, ECF No. 75-1.) Plaintiffs argue that both are subject to specific personal jurisdiction. (Pls.' Omnibus Memo 9, ECF No. 80-1.)

This case comes before the Court under 28 U.S.C. § 1332(a), the diversity jurisdiction statute, so Indiana law applies to the personal jurisdiction analysis. Fed. R. Civ. P. 4(k)(1)(A); *Daimler AG v. Bauman*, 571 U.S. 117, 125 (2014). But "[b]ecause Indiana extends personal jurisdiction to any basis 'consistent with the Federal Due Process Clause,' the sole issue is 'whether the exercise of jurisdiction comports with the limits imposed by federal due process.'" *Patterson v. Chiappa Firearms, USA, Ltd.*, No. 1:20-CV-01430-JPH-MG, 2021 WL 4287431, at *1 (S.D. Ind. Sept. 21, 2021) (citing *Advanced Tactical Ordnance Sys., LLC v. Real Action Paintball, Inc.*, 751 F.3d 796, 800 (7th Cir. 2014); Ind. Trial Rule 4.4(A)).

The Seventh Circuit gives a three-part test for specific personal jurisdiction:

First, the defendant's contacts with the forum state must show that it purposefully availed itself of the privilege of conducting business in the forum state or purposefully directed its activities at the state. Second, the plaintiff's alleged injury must have arisen out of the defendant's forum-related activities. And finally, any exercise of personal jurisdiction must comport with traditional notions of fair play and substantial justice.

NBA Props., 2022 WL 3367823 at *4 (quoting *Curry*, 949 F.3d at 398). That three-part test comes at the end of a long line of cases working toward an answer to the underlying due process question:

The ultimate constitutional standard for the exercise of specific jurisdiction has been the same since the Supreme Court first abandoned strict territorial jurisdiction: is it fair and reasonable to call the defendant into the state's courts to answer the plaintiff's claim?

uBID, 623 F.3d at 426 (citing *International Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

i. Minimum Contacts

The first prong of the specific jurisdiction test "look[s] to see if there are 'minimum contacts' between the defendant and the forum State." *Lexington Ins. Co. v. Hotai Ins. Co.*, 938 F.3d 874, 878–79 (7th Cir. 2019) (citing *World-Wide Volkswagen*, 444 U.S. at 291; *Int'l Shoe*, 326 U.S. at 316). This is a "broad standard" and "the contacts supporting specific jurisdiction can take many different forms." *uBID*, 623 F.3d at 426. "The essential point of the inquiry is to 'ensure that an out-of-state defendant is not bound to appear to account for merely random, fortuitous, or attenuated contacts' with the forum state." *Curry*, 949 F.3d at 398 (quoting *Dudnikov v. Chalk & Vermilion Fine Arts, Inc.*, 514 F.3d 1063, 1071 (10th Cir. 2008)).

Here, the Court finds that Galella and Orthomatrix have contacts with Indiana that are more than "random, fortuitous, or attenuated." *Id.* Plaintiffs allege that the AGGA devices are made in Indiana: Galella and Orthomatrix have an exclusive agreement with John's Dental to manufacture AGGA devices to their design. (Pls.' Response Ex. 4 at 18, ECF No. 80-9.) Galella and Orthomatrix allegedly review and approve the drawings for each individual AGGA device made at John's, and John's pays Galella and Orthomatrix a royalty per AGGA sold. (Pls.' Response Ex. 2 at 50, ECF No. 80-5.) Galella has filed a Supplemental Declaration, (ECF No. 81-1), in which he denies having a contract with John's Dental but otherwise affirms that the

AGGA device is manufactured in Indiana by John's Dental and that he participates in the review and approval of AGGA devices during manufacture. Aside from the legal characterization of the John's Dental agreement as a "contract," then, the parties largely agree on the facts. Galella and Orthomatrix have outsourced the manufacturing of AGGA devices to John's Dental in Indiana. Choosing an Indiana manufacturer is "purposeful availment" of the state. *Curry*, 949 F.3d at 398.

ii. Nexus

The second requirement is "the plaintiff's alleged injury must have arisen out of the defendant's forum-related activities." *NBA Props.*, 2022 WL 3367823, at *6 (quoting *Curry*, 949 F.3d at 398). Here, Plaintiffs allege personal injury from defective AGGA devices, which were made in Indiana to Galella and Orthomatrix's design. The devices owe their existence to Indiana manufacture; the injuries they allegedly cause flow from their Indiana source. The Court finds the nexus requirement satisfied.

iii. Fair Play

Lastly, the Court must ensure that the exercise of specific personal jurisdiction "does not offend traditional notions of fair play and substantial justice." *Curry*, 949 F.3d at 402 (quoting *Int'l Shoe*, 326 U.S. at 316). Where the plaintiff has "made a threshold showing of minimum contacts, that showing is generally defeated only where the defendant presents 'a compelling case that the presence of some other considerations would render jurisdiction unreasonable.'" *Id.* (quoting *Burger King*, 471 U.S. at 477).

Here, the Court sees nothing unfair in subjecting Galella and Orthomatrix to specific personal jurisdiction in Indiana. Their business is the design, promotion, and sale of orthodontics devices. They chose to make those devices in Indiana. It is only natural that, later, they should be made to defend suits in Indiana that arise from those devices' defects. *See NBA Props.*, 2022 WL 3367823 at *9 (quoting *Curry*, 939 F.3d at 402) ("There is no unfairness in requiring a defendant to defend a lawsuit in the courts of the state where, through the very activity giving rise to the suit, it continues to gain so much.").

Because Galella and Orthomatrix have minimum contacts with Indiana, this suit arises from those contacts, and jurisdiction here is not unfair, the Court finds that specific personal jurisdiction over them is proper. Their motions on Rule 12(b)(2) grounds are denied.

B. Sufficiency of Complaint

The Court proceeds now to the Rule 12(b)(6) portions of the Galella and Orthomatrix motions. There they argue, first, that Plaintiffs' claims are governed by the Indiana Products Liability Act ("IPLA") but that neither Galella nor Orthomatrix is a "manufacturer" within the terms of the Act. (Orthomatrix Memo 5–8, ECF No. 75-1.) Second, Galella and Orthomatrix argue that the warnings provided with the AGGA are sufficient, because they warn against the very harms Plaintiffs allege. (*Id.* at 8–13.) Relatedly, they argue the warnings were sufficient under the learned intermediary doctrine, by which their warning's sufficiency is measured against the knowledge of the treating dentist, not the patient. (*Id.*) Third, Galella and

Orthomatrix argue that Plaintiffs have failed to allege alternate warnings that ought to have been provided with the AGGA. (*Id.* at 13–15.) The Court will address each argument in turn.

i. "Manufacturer"

The IPLA governs product liability actions in Indiana. *See* Ind. Code § 34-20-1-1. The IPLA applies to "all actions that are (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." *Id.* Under the IPLA, "[a] person who sells, leases or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer . . . is subject to liability for physical harm caused by that product." *Id.* § 34-20-2-1. Galella and Orthomatrix argue that they are not "manufacturers" within the meaning of the IPLA.¹

The IPLA defines its terms. "'Manufacturer', for purposes of IC 34-20, means a person or an entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer." *Id.* § 34-6-2-77(a). "'Manufacturer' includes a seller who . . . creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant

¹ The Court notes that this argument is not dispositive on a motion to dismiss. If Galella and Orthomatrix are not "manufacturers" or "sellers" under the IPLA, then the IPLA does not apply, and Plaintiffs' claims sound in ordinary common-law negligence (as indeed, some of their claims, such as the negligent-instruction-of-dentists, already may). Even if Defendants "win," then, it gets them nowhere.

control over all or a portion of the manufacturing process." *Id.* § 34-6-2-77(a)(2). And "[s]eller', for purposes of IC 34-20, means a person engaged in the business of selling or leasing a product for resale, use, or consumption." *Id.* § 34-6-2-136.

Here, Plaintiffs allege that Galella "designed" the AGGA and that Galella and Orthomatrix made "treatment plan[s] . . . for the installation of an AGGA device" and "approved an AGGA device for use." (Compl. ¶¶ 62, 66, ECF No. 53.) Plaintiffs also allege that Orthomatrix "purported to analyze patients' dental/cranio maxillofacial condition" to prepare for AGGA treatment. (*Id.* ¶ 33.) Plaintiffs allege that Galella and Orthomatrix received royalties from the sale of AGGA devices. (*Id.* ¶ 40.) The Court finds those allegations sufficient to show that Galella and Orthomatrix are "manufacturers" under the statutory definition. Galella is allegedly "a person . . . who designs . . . a product," making him a manufacturer under § 34-6-2-77(a). Orthomatrix is allegedly "an entity who . . . otherwise prepares a product" for sale, making it a manufacturer under § 34-6-2-77(a). Alternately, Orthomatrix is a "seller" under § 34-6-2-136, because it is "engaged in the business of selling . . . a product." Orthomatrix does not itself sell the AGGA, but it collects a per-sale royalty from John's Dental, which puts it "in the business" of selling the AGGA. Then, as a "seller," Orthomatrix is by extension a "manufacturer" under § 34-6-2-77(a)(2), because it allegedly exercises significant control over product specifications through its Orthologix arm.

Galella and Orthomatrix, as "manufacturers," are proper defendants under the IPLA.

ii. Sufficiency of Warnings

Failure to warn claims are cognizable under the IPLA; they sound in negligence. *Anderson v. Procter & Gamble*, 542 F. Supp. 3d 850, 855 (S.D. Ind. 2021) (citing *Weigle v. SPX Corp.*, 729 F.3d 724, 731 (7th Cir. 2013)). As the Seventh Circuit explains:

A product is also defective under the IPLA if a seller does not "properly package or label the product to give reasonable warnings of danger about the product ... when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." Ind. Code § 34-20-4-2. Put another way, [the manufacturer] had "a duty to warn with respect to latent dangerous characteristics of the product, even though there is no 'defect' in the product itself." *Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind. Ct. App. 1997).

Kaiser v. Johnson & Johnson, 947 F.3d 996, 1015 (7th Cir. 2020). Two related doctrines lower the bar for what "reasonable" warnings are required. "Under Indiana's learned-intermediary doctrine, a medical-device manufacturer can discharge [the duty to warn] by providing adequate warnings to physicians." *Id.* And "[t]he sophisticated-user defense typically exempts a manufacturer from providing warnings about a product's potential dangers when the users of the product are—or should be—already aware of them." *Brewer v. PACCAR, Inc.*, 124 N.E.3d 616, 626 (Ind. 2019). Whether or not the learned-intermediary or sophisticated-user doctrines apply, the question of "whether a warning is 'reasonable' is 'generally a question of fact for the trier of fact to resolve.'" *Kaiser*, 947 F.3d at 1015 (quoting *Cook v. Ford Motor Co.*, 913 N.E.2d 311, 319 (Ind. Ct. App. 2009)).

Galella and Orthomatrix claim that the warnings provided with the AGGA treatment plans were sufficient, first because the treating dentist was a learned intermediary and second because the warnings closely track the actual injuries

Plaintiffs allege. (Orth. Memo 8–13, ECF No. 75-1.) Those are merits defenses. They go to questions of fact. A Rule 12(b)(6) motion only tests the sufficiency of the complaint. Plaintiffs allege that the AGGA was worse than useless and that they were not "ever warned" of its dangers. (Compl. ¶¶ 25, 44.) Plaintiffs also allege that, had they or their dentists "been warned of the defects and deficiencies" of the AGGA, they would have eschewed the product. (*Id.* ¶¶ 54–55.) The Court finds that those allegations, if true, plausibly show a claim to relief under the IPLA. Plaintiffs need do no more at this stage.

iii. Proposed Warnings

The parties dispute whether Plaintiffs sufficiently plead alternate, "proposed warnings." (Ortho. Memo 13–15, ECF No. 75-1; Pls.' Memo 21–23, ECF No. 80-1.) The Court is somewhat perplexed by the dispute. The IPLA does not mention or otherwise require "proposed warnings" to proceed on a failure to warn theory. *See generally* Ind. Code §§ 34-20-2-2, -4-2. Plaintiffs to recover on a failure to warn theory will have to show that "the seller . . . could have made [reasonable] warnings or instructions available." *Id.* § 34-20-4-2. At present, though, Plaintiffs "receive the benefit of imagination, so long as the hypotheses are consistent with the complaint." *Chapman*, 875 F.3d at 848. Here, where they have sufficiently alleged a failure to warn, it is reasonable and consistent to assume that they will be able, after discovery, to show that some alternate warning was possible. At no point will Plaintiffs themselves need to invent a hypothetical sufficient warning.

Finally, the Court notes that any subsidiary dispute over the sufficiency of pleading "on information and belief" is likewise misplaced. "Pleading 'upon information and belief' is not fatal to a complaint so long as there is sufficient factual detail to support the inference of plausibility." *BMO Harris Bank N.A. v. Salin Bank & Tr. Co.*, 442 F. Supp. 3d 1075, 1083 (S.D. Ind. 2020) (citing *Green v. Beth*, 663 Fed. Appx. 471, 474 (7th Cir. 2016); *Yeftich v. Navistar, Inc.*, 722 F.3d 911, 917 (7th Cir. 2013)). Here, Plaintiffs plead "on information and belief" that their dentists would not have used the AGGA with sufficient warning of its dangers. The Court finds it plausible that the dentists would or will so testify in the course of discovery. In any event, striking those allegations would not be fatal to Plaintiffs' claims: even if, with warning, the dentists had been willing to proceed with the AGGA device, the patients might not have been. The pleading stage is too early to tell.

IV. Conclusion


Galella and Orthomatrix send their AGGA device into the world by way of John's Dental Laboratory in Terre Haute, Indiana. Galella and Orthomatrix are thus within this Court's specific personal jurisdiction for these suits arising from the injuries allegedly caused by their device.

Furthermore, Plaintiffs' Complaint is not deficient on any of the three grounds asserted by Galella and Orthomatrix in their motions to dismiss. Those motions, (ECF No. 75, 76), are therefore **denied**.

This Court previously imposed, by Order of June 27, 2022, (ECF No. 83), a stay of discovery regarding Galella and Orthomatrix pending this ruling on their motions to dismiss. That **stay is hereby lifted**; discovery may proceed.

SO ORDERED.

Date: 10/17/2022



JAMES R. SWEENEY II, JUDGE
United States District Court
Southern District of Indiana

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